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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,630	04/07/2005	Leanne Gail Robinson	Leanne	7027

7590 10/13/2009

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
10/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,630	ROBINSON ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10-18,20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,19 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending. Claims 1-9, 19, 22 are considered on the merits. Claims 10-18, 20, 21are withdrawn from consideration as being drawn to a non-elected invention.

Specification

The abstract should be **on a separate sheet.** The amended abstract does not appear on a separate sheet and cannot be properly incorporated into the as filed specification by IFW scanning.

Applicant has used paragraph numbers which do not appear in the originally filed application, and therefore the amendments cannot be properly incorporated into the originally filed specification.

The amendments to the specification are not in proper form and must be cancelled. If applicant wishes to amend the specification, the applicant should refer to the as-filed specification for page and line numbers. Please note that some of the corrections the applicant desires are not necessary, if applicant would look AT THE ORIGINALLY FILED SPECIFICATION, not the published application, this would become clear. Extensive amendments to the specification after filing is discouraged because of the confusion at the time of printing the patent which can ensue because of multiple attempts to change material. Please cancel the attempt to alter the specification submitted 6/9/09 before submitting them again and citing page and line number for insertions and deletions.

It is the originally filed specification on which is based IFW scanning, issued patent printing and the examiner's work, NOT the published application.

Information Disclosure Statement

The listing of the references on PTO 1449 is incomplete. 37 CFR 1.98(b) requires that each reference be completely identified.

THE CITATION IS STILL MISSING THE INTERNET ADDRESS [URL] WHERE IT CAN BE LOCATED, see examples 5-7 MPEP 707.05(e). IT IS STILL INCOMPLETE AND CANNOT BE CONSIDERED UNTIL THE CITATION IS CORRECT. A CORRECT CITATION ALLOWS THE PUBLIC TO RETRIEVE THE PAPER or INFORMATION, using the only the complete and correct citation.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states that $1x10^5$ *Lactobacillus* are added to the feed, also claim 2 has no units for the number of *Lactobacillus* added. It appears that this is the number of bacteria added. However, the state of the bacteria, alive dead are not mentioned. The original claim has colony forming units as the unit of measure which indictates that the bacteria are capable of replication, *i.e.* alive. If not corrected, the examiner may consider the omission of this unit to be a new matter issue in a subsequent action.

WRITTEN DESCRIPTION

Claims 1-9, 19, 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-9, 19, 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention is directed to a method of feeding cattle consisting essentially of adding at least 1unit fibrolytic enzymes to 1 X 10^5 CFU of *Lactobacillus* to the feed without ensilage, and feeding the cattle. Dependent claims are further directed to types of fibrolytic enzymes and species of *Lactobacillus*.

The guidance in the specification appears to be directed solely to commercially available "fibrolytic" enzyme and microbial preparations. Yet the claims broadly claim the use of fibrolytic enzymes and *Lactobacillus*. There are many problems with this broad claiming.

The first is that commercial enzyme preparations vary over time and there is no complete disclosure in the specification as to what the exact contents of any of the commercial preparation are. Exact contents means identity and quantity both. The commercial products have great variability in the relative proportions of the enzymes in them and may include many enzymes besides cellulase, hemi-cellulase, xylanase such as amylases, proteases, pectinases. See Beauchemin *et al.* [U] for a discussion of the variability of the commercial products with respect to the types of enzyme content (page E38) which varies with the fungus strain employed, culture conditions and growth substrate. Thus, not all commercial products are the same and they do not all have the same mixture of "fibrolytic" enzymes.

Another is that the conditions for the measurement of units of activity are not given, that is, the temperature, time, substrate, pH etc. are not given. Any determination of enzyme activity requires these parameters. The measurement of enzyme activity is a variable and depends on the manufacturer's method of expressing the activity and the conditions of the assays used (Beauchemin *et al.* [U], page E39).

Another is that the components of the ruminant enzyme products change over time according to the desire of the manufacturer (Beauchemin *et al.* [U], page E39).

Yet another is that the effects of enzyme addition are influenced by factors such as type of diets fed to the cattle and enzyme application methods (Beauchemin *et al.* [U], page E42).

Thus, the invention is incompletely described because of the use of commercial products which may be trade secrets and/or incompletely described for the reasons above.

Thus, the specification fails to completely describe how to make and use the composition for at least the reasons above, and the specification fails to reasonably convey that the inventor had possession of the claimed invention.

Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir.1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it").

The Federal Circuit has explained that a specification cannot always support expansive claim language and satisfy the requirements of 35 U.S.C. 112 "merely by clearly describing one embodiment of the thing claimed." *LizardTech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346, 76 USPQ2d 1731, 1733 (Fed. Cir. 2005).

Response to Arguments

Applicant's arguments filed 6/9/2009 have been fully considered but they are not persuasive.

Applicant urges that the specification discloses where the enzymes can be obtained, *i.e.* from Novozymes Jeffreys Biologicals, under the tradenames Xylanase, Maxicel™, EX 28000™ enzymes. It appears that these products are not completely described in either the biological literature or the patent literature and the exact contents, relative amounts of the components and method of manufacture are held as trade secrets by the manufacturer.

Applicant has not provided clear and convincing evidence that this is not the case. In fact one of the passages cited in the response supports this conclusion of the examiner. On page 16 of the response filed 6/9/09, the specification is quoted as stating "Although a primary enzyme associated with *Bacillus subtilis* exact (*sic*) is amylase, OTHER USEFUL HYDROLASES ARE OFTEN INCLUDED IN THIS PRODUCT." Capitalization for emphasis. This clearly shows that the composition of the product varies over time according to the wishes of the manufacturer which is exactly what is taught by Beauchemin *et al.*, of record.

Also, the product sheet submitted on 6/9/09 which is headed by the name "XYLANASE" states that the product from known as Xylanase has a considerable amount of pectinase added without stating the source of the pectinase or the amount of the pectinase. Also the product is disclosed as having high levels of cellulase, pentosanase. No relative amounts of these enzymes are given. No source of these enzymes is given. The products used by the inventor are not completly described, complex mixtures and are held as trade secrets by the manufacturer and may be varied according to the wishes of the manufacturer. This disclosure cannot be the basis for the claimed invention because of the lack of a complete written description, particularly with regard to the working example.

Claim Rejections - 35 USC § 102

Claims 1-8, 19, 22 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 96/17525 [N].

The claims are directed to a method of feeding cattle consisting essentially of adding at least one unit of fibrolytic enzyme and and $1x10^5$ *Lactobacillus* to feed without ensilage and feeding the cattle.

The reference is relied upon as explained below.

WO 96/17525 disclose treating livestock to maintain or increase weight or milk production comprising administering two or more of a) an obligate anaerobe, b) a facultative anaerobe such as lactic acid bacteria and c) one or more enzymes capable of degrading starch or fiber, see claims 1, 3 and 28. The enzymes are added to the feed without ensilage at between 60-600 units and the *Lactobacillus acidophilus* is at between $1X10^3$ and $1X10^{11}$ (page 10) and Examples 3-5. None of the feed mentioned in the publication contains animal protein.

Claim Rejections - 35 USC § 103

Claims 1-9, 19, 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/17525 [N].

The claims have been discussed above and are further directed to the origin of the enzymes such as being obtained from *Trichoderma viride, Aspergillus oryzae, Aspergillus niger* and *Bacillus subtilis*.

The reference has been discussed above.

As long as the enzymes have the same enzymatic activity, i.e., xylanase and cellulase activity, the specific origin of the fibrolytic enzymes is considered to be an element of experimental design, in the absence of evidence of criticality of the origin.

With regard to the functional language used to describe the dosages given to the cattle which merely describes a desired result, in the absence of evidence to the contrary, the ranges of the dosages taught in WO 96/17525 are considered to be at least overlapping.

With regard to the differences in concentrations between the instant claims and the disclosure of the prior art, see MPEP 2144.05 I. and II.

In the case where the claimed ranges overlap or lie inside ranges disclosed by the prior art, a *prima facie* case of obviousness exists.

Generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation, *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution or enzyme origins in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 6/9/09 have been fully considered but they are not persuasive.

Applicant argues that the term "consisting essentially of" eliminates the addition of an obligate anaerobe. This is not persuasive.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz* , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation

resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, , 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988).

When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.").

Also, the xylanase applicants have used in the exemplification of the invention has further components such as pectinase, pentosanase according to the product data sheet submitted 6/9/09, which do not fall under the heading of fibrolytic enzymes, which are according to the specification, cellulase, xylanase, hemi-cellulase. The claim construction "consisting essentially of" which is intended to close the claim, does not correspond to applicants' disclosure of the use of these commercial products which contain numerous other digestive enzymes and can include other nondisclosed components. Thus, again, it has not been conclusively *demonstrated* what can be included and what is excluded by the use of this term.

DECLARATION filed in response to the REQUIREMENT UNDER 37 CFR 1.105.

Applicants have submitted a declaration on 6/6/09 which states that their commercial product on sale in 1995, containing an enzyme SYSTEM and lactobacillus actually contained amylase, *Saccharomyces cerevisiae* and *Lactobacillus acidophilus*. Therefore, the examiner interprets this to mean that no fibrolytic enzymes, which appear to be defined by applicant as cellulase, hemi-cellulase or xylanase were included in the composition. The for sale composition is, therefore not applicable to the instantly claimed composition under 35 USC 102 (b) on sale bar because the compositions are distinct, i.e. have distinct components. If this interpretation is not correct, a clarification is required of the applicants in the next response.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should **specifically** point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL

disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651